K120183

MAY 11 2012

510(k) Summary
(Per 21 CFR 807.92)

1. Submitter Information

Company Name	BroadMaster Biotech Corporation
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Date Prepared	2012/1/20

2. Device Name

Proprietary Name	ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Classification Number	System, Test, Blood Glucose, Over the Counter
Classification Panel	75, Clinical Chemistry
Product Code	NBW, CGA
Regulation Number	21 CFR 862.1345 Glucose Test System

3. Predicate Device

Proprietary Name	Glucose Shepherd Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Manufacturer	BroadMaster Biotech Corporation
510(k) Number	k102316

4. Device Description

The ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System consists f the ADVOCATE® Redi-Code+ BMB-EA004S Blood Glucose meter and the ADVOCATE® Redi-Code+ BMB-BA006A Blood Glucose test strips, ADVOCATE® Redi-Code+ control solutions, lancing device, and commercially available sterilized lancets. This system utilizes amperometric method to generate a current. The size of the current is proportional to the amount of glucose

presented in the sample, providing a quantitative measure of glucose level in whole blood.

Intended Use

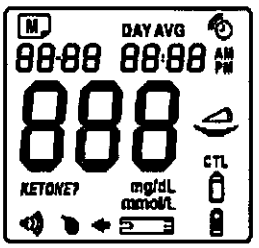
ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf, and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In additional, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis of diabetes, or for the testing of neonates.

The ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring Systems consists of the ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose meter and the ADVOCATE® Redi-Code+ BMB-BA006A Blood Glucose test strips. The ADVOCATE® Redi-Code+ BMB-EA001S meter are used only with ADVOCATE® Redi-Code+ BMB-BA006A Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf, and the thigh. The ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Meter also includes speaking functions but has not been validated for use by the visually impaired.

The ADVOCATE® Redi-Code+ control solutions are for use with the ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

5. Comparison to Predicate Device

Item	Candidate device	Predicate device
	ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System	k102316
Similarities and Differences		
Appearance		
Similarities		
Intended use	Same for both systems.	
Enzyme	Glucose Oxidase, same formula and strip design for both systems.	
Test strips	Same, BMB-BA006A test strips are for the use with both systems.	
Test sample (finger, arm...)	Same for both systems, fresh capillary whole blood (finger ,palm, forearm, upper arm, calf and thigh)	
Measuring range	Same for both systems, 20-600 mg/dL	
Hematocrit	Same for both systems, 20-60%	
Required sample volume	Same for both systems, 1.1μL	
Reaction time	Same for both systems, 5 seconds	
Coding function	Same for both systems, no coding	
Operation condition	50°F~104°F Below 85% R.H.	
MCU	TI MSP430	
Algorithm (Blood glucose concentration calculation)	Same	
The core circuit for the glucose	Same	

measurement		
Power source	Two 1.5V AAA alkaline batteries	
Weight (without batteries)	53g	
Memory	400 measurements	
Dimension(mm)	64*95*29	
LCD display		
General/ Pre-meal/ Post-meal selection	Same for both systems	
Precision	Same precision for both systems. Please refer to Attachment 12.1 Precision Study	
Linearity	Same linearity for both systems. Please refer to Attachment 12.2 Linearity Study	
Accuracy	Same accuracy for both systems. Please refer to Attachment 13.1 System Accuracy Study	
Lay user evaluation	Attachment 13.3 Customer and Alternate Site Testing Performance Evaluation. Speaking Function Evaluation Report, indicating the speaking function really increase the users' convenience, is also attached.	Easy to be used.
Interference	Same interference as the table listed in k102316. When tested following NCCLS guidelines, bilirubin, creatinine, methyldopa, galactose, maltoase, xylose, salicylate, cholesterol,hemoglobinand triglycerides at therapeutic concentrations do not significantly affect glucose results. However, these levels of the following interferences in blood may cause inaccurate test results: Acetaminophen≧ 12.5 mg/dL (Therapeutic level is 1.2-3.6 mg/dL) Ascorbic acid ≧ 7.5 mg/dL(Therapeutic level is 0.4-2.1 mg/dL) Dopamine ≧ 3 mg/dL (Therapeutic level is 0.04 mg/dL) L-dopa ≧4 mg/dL (Therapeutic level is 0.02-0.3 mg/dL)	

	Tolbutamide≧ 150 mg/dL (Therapeutic level is 3.6-7.2 mg/dL) Uric acid ≧20 mg/dL (Normal level is 2.6-7.2 mg/dL) Gentisic acid ≧ 25 mg/dL (Therapeutic level is 0.2-0.6 mg/dL) Tolazamide ≧ 15 mg/dL (Therapeutic level is 2.0-2.5 mg/dL) Mannose≧250 mg/dL(Therapeutic level is 1.15 mg/dL) Ibuprofen≧50 mg/dL(Therapeutic level is 1.0-7.0 mg/dL)	
Disinfectant Protocol	Same disinfectant protocol has been verified to work for both systems	
Altitude	Same altitude, up to 10745 feet.	
EMC testing	IEC 61326-1:2005 EN 61326-1:2006 IEC 61326-2-6:2005 EN 61325-2-6:2006 (TUV Rheinland ,Registration No.: AK 50221354 0001)	IEC 61326-1:2005 EN 61326-1:2006 IEC 61326-2-6:2005 EN 61325-2-6:2006 (TUV Rheinland ,Registration No.: AK 50186220 0001)
Glucose meter software	Blood glucose detection and data analysis algorithm is identical. (See "Attachment 13.2 Method Comparison Report")	
Control solutions cleared in 510(k) #	Same control solution level 1/2/3	
Difference		
User manual (mark differences in red when compared with the predicate)	Please refer to the section marked in red in the user manual	
Readability assessment for labeling material (User manual; test strip insert, control solutions insert)	The only difference of the labeling material is the section regarding the meter speaking function in the user manual. Per the evaluation report from Arkansas it shows users have met no problem when reading the material.	
Color and Material for the housing and button	Red ABS	Blue ABS
Additional function--English/Spanish Speaking Instruction	Yes	No
Battery Life	Over 500 times	Over 1000 times

6. Performance Studies

The performance of the ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System was studied in the laboratory and in clinical settings. The studies have demonstrated that this system meets the performance requirements of its intended use.

7. Conclusion

The laboratory testing results, clinical testing results and labeling of ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System match the Indications for Use and support the claim of substantial equivalence to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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MAY 11 2012

Re: k120183
Trade Name: Advocate® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: April 10, 2012
Received: April 11, 2012

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number k120183

Device Name:
ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System

Indications For Use:
ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf, and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In additional, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis of diabetes, or for the testing of neonates.

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The ADVOCATE® Redi-Code+ control solutions are for use with the ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k120183